

Office Action Summary

Application No.
08/737,319

Applicant(s)
Kajiwara et al.

Examiner
Bradley S. Mayhew

Group Art Unit
1652



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-5 _____ is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-5 _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: Japan 51234/1995

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2 and 5

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on 3/10/95. It is noted, however, that applicant has not filed a certified copy of the 51234/1995 application as required by 35 U.S.C. 119(b).

Drawings

2. The drawings are objected to because of the informalities listed on the enclosed form PTO 948. Correction is required.

Specification

3. The disclosure is objected to because of the following informalities: The "Brief Description of the Drawings" section was amended to refer to incorrect SEQ ID Nos. Figures 4 and 5 **only** show the nucleotide sequence of SEQ ID No: 4 and the polypeptide sequence of SEQ ID No: 1; Figures 6 and 7 **only** show the nucleotide sequence of SEQ ID No:5; and the polypeptide sequence of SEQ ID No: 2; and Figures 8 and 9 **only** show the nucleotide sequence of SEQ ID No: 6 and the polypeptide sequence of SEQ ID No: 3. Appropriate correction is required.

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Claim Rejections - 35 USC § 101

The following is a quotation of 35 U.S.C. 101:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1 and 2 are rejected under 35 U.S.C. 101 because the claims are directed to non-statutory subject matter. As drawn, the claims encompass DNA molecules that are naturally occurring. The instant rejection could be overcome by amending the claims to encompass only "isolated and purified DNA molecules."

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 2 and 4, as well as claims 3 and 5 which depend on claims 1 and 2, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 2 and 4 include the term "hybridizes." Conditions including temperature, hybridization time, ionic strength and molecular complexity combine to determine whether polynucleotides will, or will not, hybridize. The term "hybridizes" has not been defined by a particular set of such conditions either in the claim or in the specification. Without a complete definition of the hybridization conditions to be used, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

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6. Claims 1, 2 and 4, as well as claims 3 and 5 which depend on claims 1 and 2, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 2 and 4 include the term "substantially." The term is indefinite for two reasons. First, as drafted, the term acts as an adjective to modify the verb "described." Thus, Applicant is stating that the disclosed sequences are only substantially, but not fully, described. The Examiner doubts that this is Applicant's intention, and therefore it is not clear what Applicant intends. It seems most likely that Applicant intends to claim "DNA molecules that are substantially identical to the disclosed molecules." However, the term "substantially" is also indefinite when used in this way. Such a use of the term is also indefinite because a means for assessing the degree to which two molecules can differ, yet remain substantially identical, has not been defined in either the claim or the specification. Thus, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

7. Claims 1 and 2, as well as claims 3 and 5 which depend on claims 1 and 2, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "having characteristic" found in claims 1 and 2 renders the claims indefinite for two reasons: First, it is unclear whether the limitation(s) following the phrase are part of the claimed invention. If the limitation(s) following the phrase are intended to be part of the claimed

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invention, Applicant should choose language that concretely and definitely conveys what limitations are claimed. Second, it is unclear how a "DNA chain," alone, could possibly increase carotenoid production. Rather, the claimed DNA molecules encode particular enzymes, which in turn are involved in the carotenoid biosynthetic pathway. Applicant may wish to consider whether the following language more clearly conveys what Applicant intends to claim:

1. An isolated and purified DNA molecule encoding the *Phaffia rhodozyma* IPP isomerase set forth in SEQ ID No:1.
2. An isolated and purified DNA molecule encoding the *Haematococcus pluvialis* IPP isomerase set forth in SEQ ID No:2.

8. Claims 3, 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "characterized by" renders the claim indefinite because it is unclear whether the steps following the phrase are part of the claimed invention. If the steps following the phrase are intended to be part of the claimed invention, Applicant should choose language that concretely and definitely conveys what steps are claimed. For example, Applicant may wish to consider substituting the phrase "comprising the steps of" in place of the phrase "characterized by."

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9. Claims 1, 2, 3, 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims include relative terms which render the claims indefinite. Claims 1 and 2 include the term "increasing" and claims 3, 4 and 5 include the term "higher." In each case, the claims fail to establish a baseline for comparisons. That is, answers to questions "higher than what?" and "increasing from what?" are not readily apparent. The claims also fail to concretely define degree of change encompassed by the terms "increasing" and "higher" That is, an answer to questions "by how much?" is also not readily apparent. Without such information, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1, 2 and 4, as well as claims 3 and 5 which depend on claims 1 and 2, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides that encode the polypeptides of SEQ ID Nos: 1 and 2, does not reasonably provide enablement for all possible polynucleotides that "hybridize[]" to such polynucleotides. The specification does not enable any person skilled in the art to which it pertains, or with which

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it is most nearly connected, to make and use the invention commensurate in scope with the claim.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, unpredictability in the art, the amount of experimentation required, and the amount of direction or guidance presented.

The claim is drawn to encompass all polynucleotides that "hybridize[]" to sequences encoding the amino acid sequence of SEQ ID Nos:1 and 2 . The specification fails to describe a particular set of hybridization conditions that should be used for assessing whether molecules "hybridize[]." Because these hybridization conditions are not specified, the claims broadly encompass an extremely large number of polynucleotides, including a substantial number of species which lack significant complementarity to those that encoded the polypeptides of SEQ ID Nos:1 and 2. Since conditions including temperature, hybridization time, ionic strength and molecular complexity combine with the degree of nucleotide complementarity to determine the degree of hybridization, predictability of polynucleotides which hybridize requires knowledge of and guidance with regard to which conditions, if any, to modify and which to maintain as well as detailed knowledge of the ways in which polynucleotides behave in each set of conditions. Because it is beyond routine experimentation in the art to attempt all possible conditions with each individual polynucleotide, the skilled artisan would require guidance to make and use polynucleotides in a manner reasonably correlated with the scope of the claim. Without such guidance, the experimentation left to those skilled in the art is undue.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al (Journal of Biological Chemistry, vol 264, no 32, pages 19169-19175). Anderson et al teach DNA encoding a *Saccharomyces cerevisiae* IPP isomerase. While the DNA taught by Anderson et al is not identical to the DNA set forth in SEQ ID Nos: 4 or 5, it is “substantially” similar to both of the claimed DNA molecules. Furthermore, the DNA taught by Anderson et al would be expected to “hybridize[]” to the DNA set forth in SEQ ID Nos: 4 or 5 under appropriate conditions. Thus, the reference of Anderson et al anticipates the claims.

Subject Matter Free of the Prior Art

12. Claims 1 and 2 are drawn in part to DNA molecules encoding IPP isomerases. While a DNA molecule encoding an IPP isomerases similar to those set forth in SEQ ID Nos:1 and 2 has been reported by Anderson et al., DNA molecules encoding the particular *Phaffia rhodozyma* IPP isomerase set forth in SEQ ID No:1 and the *Haematococcus pluvialis* IPP isomerase set forth in SEQ ID No:2 are novel and non-obvious over the published prior art. The Examiner notes Cunningham et al. disclose DNA encoding a *Haematococcus pluvialis* IPP isomerase that is

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nearly identical to the IPP isomerase set forth in SEQ ID No:2 of the instant application (See SEQ ID Nos:11-12 and 14-15 of US Patent 5,744,341, filed March 29, 1996 and issued April 28, 1998)

Methods using DNA molecules encoding the particular IPP isomerases set forth in SEQ ID Nos:1 and 2 for enhancing the production of carotenoids in carotenoid-producing microorganisms, as claimed in claims 3 and 5, are also found to be novel and non-obvious over the published prior art.

Claim 4 is drawn in part to a method of using the DNA molecule encoding the IPP isomerase set forth in SEQ ID No:3 to enhance the production of carotenoids in carotenoid-producing microorganisms. A DNA molecule encoding the IPP isomerase set forth in SEQ ID No:3 was first disclosed by Anderson et al. However, the reference of Anderson et al does not suggest using a DNA molecule encoding an IPP isomerase to enhance the production of carotenoids in carotenoid-producing microorganisms. A thorough search of the literature has not uncovered any other reference that was publicly available at the time of the invention that anticipates or make obvious the use the IPP isomerase set forth in SEQ ID No:3 in methods to enhance the production of carotenoids in carotenoid-producing microorganisms. The Examiner notes Cunningham et al. claim that they "discovered that the inclusion of an IPP isomerase gene increases the supply of substrate for the carotenoid pathway; thereby enhancing the production of carotenoid endproducts." (See column 1, line 67 to column 2, line 3 of US Patent 5,744,341, filed March 29, 1996 and issued April 28, 1998)

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Advisory Information

13. No claims are in a condition for allowance.


14. **Any inquiry concerning this communication or earlier communications should be directed to Bradley S. Mayhew whose telephone number is (703) 308-9437. The examiner can normally be reached Monday-Friday from 9:30 am to 6:00 pm.**

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at (703) 308-4216. The fax phone number for Official Papers to this Group is (703) 305-3014 or (703)308-4242. The fax phone number for Unofficial Papers to the Examiner is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Bradley S. Mayhew
August 15, 1998



KEITH D. HENDRICKS
PRIMARY EXAMINER
GROUP 1800